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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,945

01/26/2004

David Tsai

03-10-2151

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TROJAN LAW OFFICES

9250 WILSHIRE BLVD

SUITE 325

BEVERLY HILLS, CA 90212

EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/764,945	<b>Applicant(s)</b> TSAI, DAVID	
	<b>Examiner</b> AMBER D. STEELE	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12-13, 15, and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-17 are currently pending.

The amendment to the claims received on May 22, 2008 amended claim 11.

Claims 11, 14, and 16 are currently under consideration.

### ***Election/Restrictions***

2. Applicant elected, without traverse, Group IV (claims 11, 14, and 16) in the reply filed on December 18, 2007. Claims 1-10, 12-13, 15, and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

### ***Priority***

3. The present application claims status as a CIP of 10/267,706 (filed October 8, 2002; now U.S. Patent 7,238,662) which is a CIP of 10/145,682 (filed May 14, 2002; now U.S. Patent 6,720,311) which is a CIP of 09/902,208 (filed July 9, 2001; now U.S. Patent 6,737,402) which is a CIP of 09/414,136 (filed October 7, 1999; now U.S. Patent. 6,258,779) which is a CIP of 09/149,878 (filed September 8, 1998; now U.S. Patent 5,994,298) which is a CIP of 08/993,432 (filed December 18, 1997).

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 10/267,706; 10/145,682; 09/902,208; 09/414,136; 09/149,878; and 08/993,432, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. None of the prior-filed applications disclose alpha 1-acid glycoprotein or methods of preparing zinc charged alpha 1-acid glycoprotein. Therefore, the present priority date is the filing date of the present application (i.e. January 26, 2004).

#### ***Invention as Claimed***

5. A process for preparing zinc charged alpha 1-acid glycoprotein comprising: (a) incubating said alpha 1-acid glycoprotein in solution with a chelating agents, (b) isolating naked alpha 1-acid glycoprotein from step (a), (c) incubating said naked alpha 1-acid glycoprotein in solution with zinc acetate, (d) isolating zinc charged alpha 1-acid glycoprotein from the solution in step (c), and variations thereof.

Please note: the (a) suitable for treatment of cancer cells (claim 11) and (b) apoptotic activity (claims 14 and 16) claim language is considered intended use language for the final product produced by the presently claimed method and is not provided patentable weight. In addition, any method reciting all of the method steps and reagents as presently claimed would produce a product with the same inherent properties as the final product as claimed. Please refer to MPEP § 2106, section C; § 2111.02, section II; and § 2112.02.

### **Withdrawn Objections**

6. The objection to the disclosure regarding the Patent numbers in the first line of the specification is withdrawn in view of the amendment to the specification received on May 22, 2008.

7. The objection to claim 11 is withdrawn in view of the claim amendments received on May 22, 2008.

### **Withdrawn Rejection**

8. The rejection of claims 11, 14, and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Tsai et al. U.S. Patent 6,720,311 (effective filing date of December 18, 1997); Lebreton et al. J. Clin. Invest. 64: 1118-1129, 1979; and Aebersold et al. U.S. Patent 7,183,118 (effective filing date of May 9, 2003) is withdrawn in view of an inadvertent error (i.e. U.S. Patent 6,720,311 is by Tsai/single inventor and not Tsai et al./more than one inventor).

### **New Rejections**

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Tsai U.S. Patent Application Publication 2001/0049356 (published December 6, 2001) and Lebreton et al. J. Clin. Invest. 64: 1118-1129, 1979.

For present claim 11, Tsai teaches methods for preparing zinc charged serum proteins including fetuin (i.e. alpha 2-HS glycoprotein) which is a member of the acute-phase and seromucoid class of proteins comprising (a) incubating bovine serum albumin or fetuin with a chelating agent (i.e. EDTA), (b) isolating “naked” fetuin, (c) incubating “naked” fetuin with zinc acetate, and (d) isolating zinc charged fetuin (please refer to the entire specification particularly the abstract; Figures 1-3; and paragraphs 116-129, 136, 141-148; claims 1-9).

For present claim 14, Tsai teaches methods for preparing zinc charged serum proteins including fetuin (i.e. alpha 2-HS glycoprotein) which is a member of the acute-phase and seromucoid class of proteins comprising (a) incubating bovine serum albumin or fetuin with a chelating agent (i.e. EDTA), (b) isolating “naked” fetuin, (c) incubating “naked” fetuin with zinc, (d) isolating zinc charged fetuin, (e) drying the zinc charged fetuin (i.e. EtOH drying), and (f) isolating peptide fragments of zinc charged fetuin (please refer to the entire specification particularly the abstract; Figures 1-3; and paragraphs 116-129, 136, 141-148; claims 1-9).

However, Tsai does not teach zinc supercharging of other seromucoid proteins.

For present claims 11 and 14, Lebreton et al. teach that both fetuin (i.e. alpha 2 HS glycoprotein) and orosomucoid (i.e. alpha 1-acid glycoprotein) are acute phase serum proteins (i.e. seromucoid class) and teach methods of isolating the proteins from human serum via zinc affinity chromatography and EDTA elution (please refer to the entire reference particularly the abstract; paragraph spanning the left and right columns of page 1119; page 1121, left column; page 1123, right column).

All the claimed elements (e.g. acute phase seromucoid protein alpha 1-acid glycoprotein, zinc, chelators) were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods (e.g. utilizing chelators, ability of proteins to bind metals including zinc) with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Alternatively, the claim would have been obvious because the substitution of one known element (i.e. fetuin) for another (i.e. alpha 1-acid glycoprotein) would have yielded predictable results (e.g. a positive metal can bind negatively charged protein residues, etc.) to one of ordinary skill in the art at the time of the invention. See *KSR Int'l Co. V. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Tsai U.S. Patent Application Publication 2001/0049356 (published December 6, 2001); Lebreton et al. J. Clin. Invest. 64: 1118-1129, 1979; and Aebersold et al. U.S. Patent 7,183,118 (effective filing date of May 9, 2003).

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For present claim 16, Tsai teaches methods for preparing zinc charged serum proteins including fetuin (i.e. alpha 2-HS glycoprotein) which is a member of the acute-phase and seromucoid class of proteins comprising (a) incubating bovine serum albumin or fetuin with a chelating agent (i.e. EDTA), (b) isolating “naked” fetuin, (c) incubating “naked” fetuin with zinc acetate, (d) isolating zinc charged fetuin, and (e) isolating peptide fragments of zinc charged fetuin (please refer to the entire specification particularly the abstract; Figures 1-3; and paragraphs 116-129, 136, 141-148; claims 1-9).

However, Tsai does not teach zinc supercharging of other seromucoid proteins.

For present claim 16, Lebreton et al. teach that both fetuin (i.e. alpha 2 HS glycoprotein) and orosomucoid (i.e. alpha 1-acid glycoprotein) are acute phase serum proteins (i.e. seromucoid class) and teach methods of isolating the proteins from human serum via zinc affinity chromatography and EDTA elution (please refer to the entire reference particularly the abstract; paragraph spanning the left and right columns of page 1119; page 1121, left column; page 1123, right column).

However, neither Tsai nor Lebreton et al. teach papain digestion of proteins.

For present claim 16, Aebersold et al. teach protease digestion of various glycoproteins including alpha 1-acid glycoprotein and alpha 2-HS glycoprotein (i.e. fetuin) with papain (please refer to the entire specification particularly Figures 1 and 16; column 11, lines 56-67; Tables 4-5 and 7).

All the claimed elements (e.g. acute phase seromucoid protein alpha 1-acid glycoprotein, zinc, chelators, papain) were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods (e.g. utilizing chelators, utilizing proteases



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including papain, ability of proteins to bind metals including zinc) with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Alternatively, the claim would have been obvious because the substitution of one known element (i.e. fetuin and proteinase K) for another (i.e. alpha 1-acid glycoprotein and papain) would have yielded predictable results (e.g. papain will cleave cysteine residues of proteins, a positive metal can bind negatively charged protein residues, etc.) to one of ordinary skill in the art at the time of the invention. See *KSR Int'l Co. V. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsai U.S. Patent Publication 2003/0087809.

### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Patent Examiner, Art Unit 1639

August 19, 2008